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No. 99-753

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

ABBOTT LABORATORIES,

Petitioner,

v.

GENEVA PHARMACEUTICALS, INC.,
NOVOPHARM LTD. and INVAMED, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF

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INTRODUCTION

Petitioner Abbott Laboratories ("Abbott") submits this reply brief in support of its petition for writ of certiorari to address the question, raised in the Brief In Opposition For Geneva Pharmaceuticals, Inc., of whether the so-called "inherency doctrine" supports the Federal Circuit's holding in this case.

ARGUMENT

THE INHERENCY DOCTRINE IS INAPPLICABLE HERE AND OFFERS NO SUPPORT FOR THE FEDERAL CIRCUIT'S ERRONEOUS HOLDING THAT CONCEPTION IS IRRELEVANT TO THE "ON SALE BAR" ANALYSIS.

Respondent Geneva Pharmaceuticals, Inc. ("Geneva") devotes most of its opposition brief to the proposition that a patent cannot be obtained merely for discovering "a new property or use of a previously known composition." Brief In Opposition, pp. 4-5, *quoting In re Spada*, 911 F.2d 705, 706 (Fed. Cir. 1990). This "inherency doctrine" is inapplicable here. Abbott's discovery of Form IV terazosin hydrochloride was *not* a discovery of a new property of a previously known composition. Abbott's discovery of a new polymorph of terazosin hydrochloride was instead a discovery of an entirely new, and independently patentable, composition of matter. *See Zenith Laboratories v. Bristol-Myers Squibb Co.*, 19 F.3d 1418 (Fed. Cir.), *cert. denied*, 513 U.S. 995 (1994). It is in fact well settled, and not disputed by Geneva, that a new crystalline form of a chemical compound has *not* been invented or conceived, and is *not* patentable, "where there has been no recognition or appreciation of the existence of the new form." *Silvestri v. Grant*, 496 F.2d 593, 597 (C.C.P.A. 1974).

The "inherency doctrine" would be applicable here only if the existence of Form IV had been previously known to the art and Abbott had discovered some inherent property of that compound — that it was, for example, not flammable. No such circumstances exist here, where Form IV was *itself* unknown to the art until Abbott discovered it. The inherency cases relied upon by Geneva are therefore irrelevant to the question presented by Abbott's petition.

Geneva also contends that Abbott's petition "raises no issues of importance to the public or to industry." Brief In Opposition, p. 1. In fact, the Court of Appeals' holding that an inventor's Constitutionally-secured patent rights can be lost because of a third party's prior, unknowing manufacture and sale of a new compound undermines the basic goal of the Patent Act — to reward innovation. The Court of Appeals' holding also impairs Congress' "interest in providing inventors with a definite standard for determining when a patent application must be filed," *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 119 S. Ct. 304, 311 (1998), for under the Court's holding the one-year "on sale" period can begin and end, as it did here, without *anyone* ever realizing that a new compound had been created. Finally, the Court of Appeals' holding undermines the settled principle that "the inventor's *conception*," not the "physical embodiment of [its] idea," is the touchstone of patentability. *Pfaff*, 119 S. Ct. at 308 (emphasis added).

CONCLUSION

Summary reversal, or review by certiorari, is warranted here because the Court of Appeals' holding that the on-sale bar of section 102(b) of the Patent Act is triggered by the unknowing manufacture and sale of a new chemical compound is in direct conflict with this Court's holding in *Pfaff*, 119 S. Ct. at 311, that the process of conception must be complete before the on-sale bar can arise.

Respectfully submitted,

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